ABSTRACT

Determination of Selected Active Substance in the Preparation VII

Thesis

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Suitable HPLC methods for the determination of cinchocaine and for the determination of purity of dexamethasone in liquid pharmaceutical preparation were searched. The monolithic column Chromolith Speed ROD RP-18e 50-4.6 was used.

A mixture of water:acetonitrile; 50:50; 1,575 ml of triethylamine in 250 ml of water; was chosen as the mobile phase for cinchocaine hydrochloride; pH of the mobile phase was adjusted to 7.0 by orthophosphoric acid. Flow rate was 3 ml/min, column temperature 25 ºC, injected volume 5 µl and UV detection at 325 nm. Linearity, specificity, precision and accuracy were tested under these conditions.

For purity of dexamethasone gradient elution was chosen. Mobile phase A: water, acetonitrile (80:20) and mobile phase B in the rate of 93:7; pH of the mobile phase was adjusted to 7.0 by orthophosphoric acid. Mobile phase B: water, acetonitrile (75:25); 1,05 ml triethylamine in 250 ml water; pH of the mobile phase was adjusted to 7.0 by orthophosphoric acid. Flow rate was 4 ml/min, column temperature 25 ºC, injected volume 50 µl and UV detection at 238 nm. The method was found to be precise, specific and linear.